IN THE UNITED STATES DISTRICT COURT FOR THE DISTRICT OF DELAWARE

NEXUS PHARMACEUTICALS, INC.,

Plaintiff,

v.

Civil Action No. 22-1233-GBW

EXELA PHARMA SCIENCES, LLC,

Defendant.

Kelly E. Farnan, Christine D. Haynes, RICHARDS, LAYTON & FINGER, P.A., Wilmington, DE; Imron T. Aly, Kevin Nelson, Matthew T. Wilkerson, Julie A. Vernon, ARENTFOX SCHIFF LLP, Chicago, IL; Ahmed M.T. Riaz, Max Heckendorn, ARENTFOX SCHIFF LLP, New York, NY.

Counsel for Plaintiff

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Counsel for Defendant

MEMORANDUM OPINION

July 18, 2025 Wilmington, Delaware

GREGORY B. WILLIAMS UNITED STATES DISTRICT JUDGE

Pending before the Court is Exela's *Daubert* Motion to Exclude Mr. Hofmann's Lost Profits and Price Erosion Opinions ("Motion" or "*Daubert* Motion") (D.I. 204), which has been fully briefed (D.I. 206; D.I. 232; D.I. 254). For the following reasons, the Court denies Exela's *Daubert* Motion (D.I. 204). Exela's Request for Oral Argument (D.I. 262) is denied-as-moot.

I. BACKGROUND

This patent-infringement action concerns U.S. Patent Nos. 11,464,752 ("the '752 patent"), 11,426,369 ("the '369 patent"), and 11,571,398 ("the '398 patent") (together, the "Asserted Patents"). *See* D.I. 200 at 1. The Asserted Patents generally relate to 5 mg/mL ephedrine sulfate products.

Exela hired Mr. Ivan Hofmann ("Mr. Hofmann") "to offer opinions on lost profits and price erosion damages." *See* D.I. 206 at 1. In Mr. Hofmann's reports, he opines that "Nexus would have made every one of Exela's sales at three times Exela's price" and that "Nexus would have made every sale it made in the actual world for \$13 more per syringe in the 'but for' world." *See* D.I. 206 at 1. In other words, Mr. Hofmann opines that (1) for every accused product Exela sold at the reduced generic price, Nexus would have sold the same number of its products at the premium price that Nexus sold its products prior to Exela introducing its products to the market, and (2) absent Exela selling its accused generic products, Nexus would have sold all of its products at the premium price. *See generally*, D.I. 206 at 1.

¹ The Plaintiff is Nexus Pharmaceuticals, Inc. ("Nexus" or "Plaintiff"). The Defendant is Exela Pharma Sciences, LLC ("Exela" or "Defendant").

In its opening brief in support of its *Daubert* Motion, Exela contends that these "assumptions" from Mr. Hofmann are "flawed" in that they "fly in the face of the bedrock economic principle of price elasticity—i.e., that consumers will usually purchase fewer units of a product at a higher price." D.I. 206 at 1. In particular, Exela contends that Mr. Hofmann "failed to provide any analysis" on price elasticity. D.I. 206 at 15. Thus, Exela seeks exclusion of Mr. Hofmann's opinions and testimony on lost profits and price erosion as unreliable. D.I. 206 at 1, 3. "Without these excluded opinions," Exela contends that "Nexus has no evidence to support its lost profits claim, warranting summary judgment of no lost profits." D.I. 206 at 15.

II. LEGAL STANDARD

In *Daubert v. Merrell Dow Pharmaceuticals, Inc.*, the U.S. Supreme Court held that Federal Rule of Evidence 702 creates "a gatekeeping role for the [trial] judge" in order to "ensur[e] that an expert's testimony both rests on a reliable foundation and is relevant to the task at hand." 509 U.S. 579, 597 (1993). Rule 702 provides:

A witness who is qualified as an expert by knowledge, skill, experience, training, or education may testify in the form of an opinion or otherwise if the proponent demonstrates to the court that it is more likely than not that: (a) the expert's scientific, technical, or other specialized knowledge will help the trier of fact to understand the evidence or to determine a fact in issue; (b) the testimony is based on sufficient facts or data; (c) the testimony is the product of reliable principles and methods; and (d) the expert's opinion reflects a reliable application of the principles and methods to the facts of the case.

Fed. R. Evid. 702. As the Third Circuit has explained:

Rule 702 embodies a trilogy of restrictions on expert testimony: qualification, reliability and fit. Qualification refers to the requirement that the witness possess specialized expertise. We have . . . [held] that a broad range of knowledge, skills, and training qualify an expert. Secondly, the testimony must be reliable; it must be based on the methods and procedures of science rather than on subjective belief or unsupported speculation; the expert must have good grounds for his o[r] her belief. In sum, *Daubert* holds that an inquiry into the reliability of scientific evidence under Rule 702 requires a determination as to its scientific validity. Finally, Rule 702 requires that the expert testimony . . . must be relevant for the purposes of the case and must assist the trier of fact.

Schneider ex rel. Estate of Schneider v. Fried, 320 F.3d 396, 404 (3d Cir. 2003) (cleaned up); Kuhar v. Petzl Co., No. 19-cv-3900, 2022 WL 1101580, at *7 (3d Cir. Apr. 13, 2022) (acknowledging the same trilogy).

Rule 702 "has a liberal policy of admissibility," *Pineda v. Ford Motor Co.*, 520 F.3d 237, 243 (3d Cir. 2008) (citation omitted); *see also United States v. Scripps*, 599 F. App'x 443, 447 (3d Cir. 2015) (same), as "the question of whether the expert is credible or the opinion is correct is generally a question for the fact finder, not the court," *Summit 6, LLC v. Samsung Elecs. Co.*, 802 F.3d 1283, 1296 (Fed. Cir. 2015). "Vigorous cross-examination, presentation of contrary evidence, and careful instruction on the burden of proof are the traditional and appropriate means of attacking shaky but admissible evidence." *Daubert*, 509 U.S. at 596; *see Karlo v. Pittsburgh Glass Works, LLC*, 849 F.3d 61, 83 (3d Cir. 2017) (quoting *Daubert*, 509 U.S. at 596).

III. DISCUSSION

The dispositive inquiry before the Court is whether an expert in an action for patent infringement, to survive a *Daubert* challenge, must, to some degree, analyze price elasticity when opining on lost profits and price erosion damages. The answer to that inquiry is no. *See Anesta AG v. Mylan Pharms., Inc.*, No. CV 08-889-SLR, 2014 WL 3976456, at *3 (D. Del. Aug. 14, 2014) ("I agree that the issue of price elasticity was not discussed by Dr. Maness in his expert report. I have held that he was not required *per se* to do so. Moreover, the issue was apparently addressed at his deposition, and defendants have his best thoughts through that discovery tool on why he did not consider price elasticity in his analysis. Dr. Maness will be limited to the evidence of record. I decline to exclude Dr. Maness' lost profits analysis based on defendants' now rejected argument that price elasticity is always in play; that is fodder for cross examination. Therefore, both defendants' motions for partial summary judgment (D.I. 351) and to exclude the expert testimony of Dr. Maness (D.I. 360) are denied."); *VARTA Microbattery GmbH v. Audio P'ship*

LLC, No. 221CV00400JRGRSP, 2023 WL 5434854, at *4 (E.D. Tex. Aug. 23, 2023) ("EVE argues that Mr. Metzdorff uses \$2.15 as EVE's sales price—300% higher than what EVE reported—and then he multiples that price by the number of products EVE sold without considering that the increased price may reduce sales. According to EVE, Mr. Metzdorff's lost profits opinions should be excluded for using an unreliable methodology. The Court disagrees. EVE's criticisms go to the weight to be accorded to Mr. Metzdorff's opinions and not its admissibility.") (citations omitted).

The primary case upon which Exela relies is *Crystal Semiconductor Corp. v. TriTech Microelectronics Int'l, Inc.*, 246 F.3d 1336 (Fed. Cir. 2001). D.I. 206 at 1, 8-15 (citing *Crystal* over ten times). Therein, the Federal Circuit explained that, "in a credible economic analysis, the patentee cannot show entitlement to a higher price divorced from the effect of that higher price on demand for the product." *Crystal*, 246 F.3d 1336, 1357. The Federal Circuit also stated that "the patentee must also present evidence of the (presumably reduced) amount of product the patentee would have sold at the higher price." *Crystal*, 246 F.3d 1336, 1357. Nexus's reliance on *Crystal*, however, is unconvincing for at least three reasons.

First, the procedural vehicle in which the Federal Circuit and the district court below in Crystal considered the purported issues with the expert's testimony was not a Daubert motion; rather, the vehicle was a motion to remit damages. See id. at 1358.

Second, Nexus fails to identify any binding precedent which has relied on Crystal to exclude an expert's opinion and testimony on lost profits and price erosion damages where that expert's opinion and testimony did not consider price elasticity. See D.I. 206. In fact, this Court has previously denied that Crystal requires such exclusion. See Anesta, 2014 WL 3976456, at *2-3 ("Defendants argue that plaintiffs should be precluded from claiming lost profits because their

expert, Dr. Maness, failed to consider price elasticity in his lost profits analysis. . . . With respect to the substantive aspects of the dispute, I start with an analysis of defendants' primary case, Crystal Semiconductor Corp. v. TriTech Microelectronics Int'l, Inc., 246 F.3d 1336 (Fed.Cir.2001). . . . The lesson I take away from Crystal is not that the Federal Circuit has a rigid formula for judging economic analyses, but that its demand for a 'credible economic analysis' can be met by a variety of evidence—both fact and expert—depending on the facts of the case and the nature of the markets at issue. Therefore, I will not preclude the presentation of a lost profits analysis by plaintiffs. . . . Having rejected defendants' proposition that there are rigid standards applicable to every case, I decline to take the issue of lost profits damages away from the jury.").

Third, to the extent that Mr. Hofmann did not address or consider price elasticity in his lost profit analysis and/or testified during his deposition that the market is "fairly inelastic" (D.I. 232 at 2), both are "fodder for cross examination" at trial. See Anesta, 2014 WL 3976456, at *3. Indeed, the Federal Circuit has, post-Crystal, confirmed that, while "an inelastic market may be rare," whether the market is inelastic is an issue for resolution by the jury. Ericsson, Inc. v. Harris Corp., 352 F.3d 1369, 1379 (Fed. Cir. 2003) (quotation marks omitted).

Moreover, the Court is not obliged to follow the precedents that Exela identifies (see, e.g., D.I. 206 at 10) from other district courts, including those outside of this circuit. See Daubert v. NRA Grp., LLC, 861 F.3d 382, 395 (3d Cir. 2017) ("A decision of a federal district court judge is not binding precedent in either a different judicial district, the same judicial district, or even upon the same [district] judge in a different case." (alteration in original) (quoting Camreta v. Greene, 563 U.S. 692 (2011)); Wahl Clipper Corp. v. Conair Corp. & Conair LLC, No. 23-cv-00114-JCG-LDH, 2024 U.S. Dist. LEXIS 23526, at *2 (D. Del. Jan. 16, 2024) (confirming that out-of-circuit cases "are not binding on this Court").

In summary, since the law does not require that an expert's opinions on lost profits and price erosion damages in a patent infringement action address price elasticity, Mr. Hofmann's purportedly incomplete or entirely lacking analysis of price elasticity does not constitute a sufficient ground for exclusion under *Daubert* and its progeny. Instead, the Federal Circuit and this Court have instructed that, on cross-examination during trial, Exela can challenge or test Mr. Hofmann's expert opinions on lost profits and price erosion through questions about Mr. Hofmann's lack of analysis and/or consideration of price elasticity in reaching his opinions on lost profits and price erosion.

IV. CONCLUSION

For all the foregoing reasons, Exela's *Daubert* Motion to Exclude Mr. Hofmann's Lost Profits and Price Erosion Opinions (D.I. 204) is DENIED. Also, Exela's Request for Oral Argument (D.I. 262) is DENIED-AS-MOOT.